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September 15, 1993



93-RF-11078

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J. K. Hartman Assistant Manager for Transition and Environmental Restoration DOE, RFO

STATISTICAL METHODOLOGY FOR BACKGROUND AND COMPARISONS AT THE ROCKY FLATS PLANT - NMH-463-93 Ø

This letter is in response to the Department of Energy, Rocky Flats Office request (9379) for review and comments on the subject letter report developed by Dr. Richard D. Gilbert of Pacific National Laboratory. We have reviewed Dr. Gilbert's report and our comments are included in the attached. As requested, we have conducted our review in light of potential impacts to scope, schedule and cost within the Interagency Agreement (IAG) implementation program. Our review consisted of technical and program experts within Environmental Restoration Management and select contractors, EG&G Statistical Applications (SA) Department, including the outside expertise of Dr. K. Crump of ICF-Kaiser. As requested, comments from SA are attached.

In summary, Dr. Gilbert's proposed methodology is conceptually sound and comprehensive though, somewhat in excess of what is typical in the hazardous waste industry and Environmental Protection Agency, Region VIII. Some technical issues such as exact testing procedures and handling of nondetection laboratory results remain outstanding. The cost and schedule implementation impacts could be significant ranging from \$30,000 up to \$120,000 for some Operable Units and requiring from one to five months depending on the complexity of the site.

It is likely that adoption of Dr. Gilbert's methodology will require negotiation of IAG milestones. If you have any questions regarding this issue, please contact D. M. Smith of Environmental Engineering & Technology at extension 8636.

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Attachments: As Stated (2)

ATTACHMENT A

Cost and Schedule Impacts

Direct costs associated with implementing the "Gilbert Method" on OU-specific projects will vary depending on the complexity and size of the data set. The estimated additional cost and schedule impact for implementation on OU 3 (a relatively straight forward and small data set) is approximately \$30,000 and a four to six week period of performance extension. On OU 7, (a more complex and significantly larger data set) the impact is estimated to be closer to \$90,000 with an added schedule effect of approximately 8 weeks.

These estimated \$30,000 to \$90,000 costs, and 1 to 2 month schedule impacts assume: no significant startup impacts (such as a rough learning curve runnup or software development and implementation problems) and do not account for impacts in preparation of the Human Health Baseline Risk Assessment (HHBRA) Contaminant Of Concern (COC) Technical Memorandum (TM). Therefore, they should be considered as somewhat optimistic and actual cost and schedule impacts could be greater. The cost of producing, negotiating and obtaining approval of the HHBRA COC TM will also increase by approximately \$15,000. Thus, the actual anticipated cost impact could be in the range of \$50,000 to \$100,000 per OU (some efficiency would be expected on later OU's owing to becoming more familiar with the process). In the extreme case with complex OU's this estimate could be low. It was estimated that for OU 2 to go back and rework the HHBRA COC TM in accordance with the Gilbert Method would cost approximately \$125,000 and require 4-5 months to complete. This range of impact would apply to a full rework of OU 1 as well.

Perhaps more important to RFO is consideration of the timing with respect to when the statistical work would actually be performed. Within the typical RFI/RI production process; receipt of laboratory data, the ensuing analysis, and production of the HHBRA COC TM has been observed to establish the critical path for attainment of the RFI/RI IAG milestone. Most of the existing IAG schedules assume production of the HHBRA COC TM within two to four weeks after receipt of all analytical data (i.e., the 100% data complete date). Adopting the "Gilbert Method" can be expected to extend the critical path production time by 1 to 2 months and will likely require negotiating IAG milestone extensions for impacted RFI/RI's as well as the sequential downstream deliverables (e.g., CMS/FS, etc.).

Technical Aspects

Technical experts generally agreed that the Gilbert Method was logical, conceptually sound in approach, and was a scientific enhancement over the OU 1/OU 2 compromise approach. The Gilbert Method is generally quite conservative in that its application will likely minimize the chance of missing site contaminants at the expense of increasing the likelihood of falsely declaring analytes as contaminants when in fact they are not. While appealing to the regulatory agencies, this aspect will tend to increase DOE's estimates of human and ecological risk through inclusion of more compounds in the risk analysis as contaminants.

Based on a review of current practices at the Lowry Landfill and Rocky Mountain Arsenal (RMA) Offpost OU, the Gilbert Method, is more conservative but technically consistent with its emphasis on inferential statistics. Dr. Gilbert's battery of tests (Phase IV) goes well beyond the methodology employed at both Lowry and RMA. Limiting the use of "benchmarks" (i.e., UTL's) to identifying anomalies is also more conservative than has been applied in the Region.

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Differing programmatic implementation and scientific opinion surfaced regarding use of the Gehan Test (a "scores test"). The test is not available in commercial software, and one author commonly cited in the environmental literature (Hesel, D.R., Less Than Obvious, *Environmental Science & Technology*, V. 24 No. 12) cautions against using "scores tests" under conditions similar to those common with RFP data sets (i.e., cases of unequal sample size and when differing censoring methods are applied between comparison groups). EG&G's SA department feels that these concerns will not compromise programmatic implementation or scientific verity.

An important issue regarding any statistical protocol was raised by EG&G's Geosciences Department who pointed out that it is probably unwise to base any decision on a heavily censored data set (e.g., non-detects in the range of 80% or greater). Preliminary information on handling of non-detection analytical results reported to RFO (93-RF-10580) indicated that parameter estimation was very sensitive to data sets with a high degree of censoring. EG&G is formulating a policy for handling non-detects and will report to RFO by October 25, 1993.

Positive Facets

The most significant and favorably viewed technical aspects commonly identified were: (1) Phase III: Data Presentation, (2) Phase IV: application of a Hot Measurement (HM) in a screening capacity, (3) Possible use of the Gehan Test (i.e., the "Scores Test" identified by A. Palachek [SA]) for data sets with multiple detection limits (also Phase IV) and (4) the use of professional judgement and geochemical analysis in Phase V.

Negative Facets

Some criticisms of the Gilbert Method dealt with the assumptions embodied into the method. Specifically: (1) establishment of suitable background(s) for comparisons, (2) use of random sampling techniques, and (3) identification of, and accounting of all spatial and temporal trends in the background and site comparison locations. These are assumptions that could undermine application of the method. In some instances, OU specific sampling programs (as detailed in various approved work plans) were not based on fulfilling these assumptions.

Other criticisms identified include: (1) though comprehensive, the Gilbert Method is considered by some to be more than necessary. For example, application of the entire Phase III component for a full suite analysis could result in over 1500 graphs, and applying a battery of tests (Phase IV) creates imbalances that could be avoided, (2) the Gehan test is not readily available on most public domain software and would require development of a specialized code for wide application, and (3) resolution of Region VIII administrative rules such as the Gansecki Rule for deleting nondetect data higher than the highest reported value and related "nondetection" issues.